II. REMARKS

A. Status of the Claims

Claims 1, 3, 5, 7, 8, 10-20 and 36-56 are pending. Claims 2, 4, 6 have been cancelled without prejudice. Claims 21-35 were previously cancelled. Claims 1, 5 and 12-20 have been amended without prejudice. New claims 36-56 have been added. Support for the new claims can be found throughout the original specification as filed, e.g., the original claims. It is respectfully submitted that no new matter has been added by virtue of the present amendment.

B. Double patenting

Claims 1-8 and 11-20 were rejected under the judicially created doctrine obviousness-type double patenting "as being unpatentable over claims 1-20 of U.S. Patent No. 6,277,384 ('384). Further, the Examiner noted that "there are a number of applications appear[ing] to be potential double patenting based on overlapping, similar, or like subject matters." The Examiner specifically noted U.S. Patent Nos. 6,275,957; 6,696,066; 6,696,088; and 6,716,499.

In response, filed herewith are terminal disclaimers with respect U.S. Patent Nos. 6,277,384, 6,375,957, and 6,696,066 in compliance with 37 C.F.R. 1.321(c).

Applicants note that the obviation of an obvious-type double patenting rejection by the filing of a terminal disclaimer is not an admission, acquiescence, or estoppel on the merits of an issue of obviousness. *See Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 873-74, 20 U.S.P.Q.2d 1392, 1394-95 (Fed. Cir. 1991).

With respect to U.S. Patent No. 6,696,088 it is respectfully submitted that the claims of this patent fail to teach or suggest an oral dosage form comprising an opioid

agonist and naltrexone or a pharmaceutically acceptable salt thereof in the ratios recited in present claim 1.

With respect to U.S. Patent No. 6,716,449, it is respectfully submitted that the claims of this patent also fail to teach or suggest an oral dosage form comprising an opioid agonist and naltrexone or a pharmaceutically acceptable salt thereof in the ratios recited in present claim 1.

C. Rejections under 35 U.S.C. § 103

1. Kreek in view of the Dr. Medzon reference

Claims 1-6, 8, 12-14 and 16-20 were rejected under 35 U.S.C. 103(a) "as being unpatentable over Kreek US 4,769,372, in view of Dr. Medzon (Clinical Toxicology Review).

The Examiner states that "it would have been obvious for one of ordinary skill in the art to modify the oral composition of Kreek using naltrexone as a suitable opioid antagonist, because Dr. Medzon teaches naltrexone by virtue of its' structural similarities to naloxone, shares the same properties exhibits by naloxone (page 1, 5th paragraph), because Dr. Medzon teaches naltrexone exhibits longer active opioid antagonists (page 1, 1st paragraph), and Dr. Medzon teaches naltrexone has a high range of safety (page 3, 2nd paragraph)."

Kreek describes "dosage units comprising in combination opioid analgesics or antitussives and selected opioid antagonist which are **substantially devoid of systemic antagonist activity when administered orally**." (emphasis added). See abstract.

It is respectfully submitted that naltrexone is not an opioid antagonist substantially devoid of systemic antagonist activity when administered orally. The Dr. Medzon reference indicates that "Naltrexone is approved by the FDA for use in opioid

detoxification, and alcohol detoxification programs in known substance abusers" and that "Naltrexone is available only in the oral form." See page 1, second paragraph of Clinical Toxicology Review.

In view of the foregoing, it is respectfully submitted that one of ordinary skill in the art would not be motivated in view of the Dr. Medzon reference to modify the oral composition of Kreek to include naltrexone as an opioid antagonist.

Therefore, it is respectfully requested that the 35 U.S.C. 103(a) rejection over Kreek in view of the Dr. Medzon reference be removed.

2. Kreek in view of the Dr. Medzon reference and Mitch et al.

Claims 7, 10, 11 and 15 were rejected under 35 U.S.C. 103(a) "as being unpatentable over Kreek US 4,769,372, in view of Dr. Medzon (Clinical Toxicology Review) and Mitch et al. US 5,998,434.

This rejection is respectfully traversed. In view of the arguments presented above, it is respectfully submitted that one of ordinary skill in the art would not arrive at the present invention in view of Kreek and the Dr. Medzon reference. It is respectfully submitted that Mitch et al. do not cure the deficiencies of Kreek and the Dr. Medzon reference as discussed above.

Therefore, it is respectfully requested that 35 U.S.C. 103(a) rejection over Kreek, in view of the Dr. Medzon reference and Mitch et al. be removed.

3. Kreek in view of the Dr. Medzon reference and the FDA consumer reference

Claim 10 was rejected under 35 U.S.C. 103(a) "as being unpatentable over Kreek US 4,769,372, in view of Dr. Medzon (Clinical Toxicology Review) and FDA consumer."

This rejection is respectfully traversed. In view of the arguments presented above, it is respectfully submitted that one of ordinary skill in the art would not arrive at the present invention in view of Kreek and the Dr. Medzon reference. It is respectfully submitted that the FDA Consumer reference does not cure the deficiencies of Kreek and the Dr. Medzon reference as discussed above.

Therefore, it is respectfully requested that 35 U.S.C. 103(a) rejection over Kreek, in view of the Dr. Medzon reference and the FDA consumer reference be removed.

III. CONCLUSION

It is now believed that the above-referenced rejections have been obviated and it is respectfully requested that the rejections be withdrawn. It is believed that all claims are now in condition for allowance.

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if he believes that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,

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By: _____

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